2 510(k) Summary

Date Prepared: September 8, 2011

Manufacturer's Information / Contact Person

Manufacturer

Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact

Melinda Swanson
Sr. Director, Regulatory Affairs and Clinical Research
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General Information

Trade Name	VSI Guidewire
Common / Usual Name	Guidewire
Classification Name	870.1330; DQX; Wire, Guide, Catheter; Class II: A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.
Predicate Device(s)	VascuPuncture™ PICC Guidewire (K012861 and K043398, Neometrics, Inc.)

Device Description

The VSI Guidewire is available in a diameter of 0.018" and lengths ranging from 40-130 cm. The device is available with a stainless steel or nitinol shaft with a stainless steel or tungsten tip. Some models are PTFE coated to increase lubricity.

Intended Use / Indications

The VSI Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. The device is not indicated for use in the coronary or cerebral vasculature.

Technological Characteristics

The subject and predicate devices are identical in design, materials, and construction. There are no differences in technological characteristics.

Substantial Equivalence and Summary of Studies

Because the subject and predicate devices are identical in design, materials, construction, and Indications for Use, no performance testing was conducted or is warranted in support of the determination of substantial equivalence. Further processing conducted by VSI leads to no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vascular Solutions, Inc.
c/o Melinda Swanson
6464 Sycamore Court
Minneapolis, MN 55369

OCT 2 7 2011

Re: K112631
Trade/Device Name: VSI Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: September 8, 2011
Received: September 9, 2011

Dear Ms. Swanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112631

Device Name: VSI Guidewire

Indications for Use:

The VSI Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. The device is not indicated for use in the coronary or cerebral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112631